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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,511	01/19/2001	Sean A. McCarthy	10147-65	9759
			(MPI2000-537OMNI)	
			EXAMINER	
			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

7590 11/04/2003
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225 FRANKLIN STREET
BOSTON, MA 02110-2804

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/766,511	Applicant(s) MCCARTHY ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 13-30 and 32-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12, 31 and 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED OFFICE ACTION

Applicant's amendment filed on 20 August 2003 is acknowledged and entered. Following the amendment, claims 1, 2, 4 and 12 are amended, and the new claims 44-46 are added.

Currently, claims 1-46 are pending, and claims 1-7, 12, 31 and 44-46 are under consideration.

The Declaration under 37 CFR 1.132 filed on 18 August 2003 is sufficient to overcome the rejection of claims 1, 2 and 12 based upon lack of the proper deposit statement under 35 U.S.C. 112, first paragraph.

Withdrawal of Objections and Rejections:

The enablement rejection of claims 1, 2 and 12 for lack of the proper deposit statement under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's declaration.

The rejection of claims 1 and 12 for lack of written description, under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

The rejection of claims 1-3, 5-7, 12 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The prior art rejections of claims 1, 3-7 and 12 made in the last Office Action is withdrawn in view of applicant's amendment.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 12 and 31 remain rejected, and claims 44-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific,

or well-established utility, for the reasons of record set forth in the last Office Action, paper No. 17, mailed on 23 April 2003, at pages 3-5.

Applicants argument filed on 20 August 2003 has been fully considered, but is not deemed persuasive for reasons below.

At pages 13-14 of the response, the applicant argues that applicant has provided sufficient evidence to establish that human TANGO405 is a lectin ortholog of dectin-2 as they share 89% sequence homology, and a single C-type lectin domain in the COOH terminus, that a translational frame shift in murine TANGO405 results in an amino acid sequence identical to dectin-2, and that human TANGO405 is derived from a mixed lymphocyte reaction, indicating similar biological function to dectin-2. This argument is not persuasive because, as addressed in the last Office Action, generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein, and proteins of a same family, sharing a high degree of sequence similarity, may have diverse, and sometimes even opposite biological activities and functions. With respect to the issue of the translational frame shift, the art has not established that such is meaningful as to identifying proteins between species, or predicting protein functions. With respect to that human TANGO405 is derived from a mixed lymphocyte reaction, again, it is unclear what is its specific biological significance, as many factors may derive from such a reaction, and whether it stimulates such a reaction, or is resulted from such a reaction. The present specification does not disclose any functional property or biological significance that is *directly associated with the human TANGO405*, and further research to identify such is required, which renders the instant invention not substantial. Mere fact that the human TANGO405 share high degree of sequence homology to murine dectin-2 is an interesting invitation for further research and experimentation to confirm the exact role and functional property of the protein. Upon further research, the human TANGO405 may indeed be a lectin ortholog of dectin-2, and have similar function as dectin-2. However, these further research and experimentation is a part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1646

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 12 and 31 remain rejected, and claims 44-46 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the last Office Action, paper No. 17, at page 5.

Applicants argument filed on 20 August 2003 has been fully considered, but is not deemed persuasive for the reasons above.

Furthermore, even if the specification taught how to use human TANGO405, enablement would remain not being commensurate in scope with claim 1, and the dependent claims 3-7, 12, 45 and 46, for the reasons of record set forth in the last Office Action, paper No. 17, at pages 5-6.

Applicants argument filed on 20 August 2003 has been fully considered, but is not deemed persuasive for reasons below.

At page 15 of the response, the applicant argues that the claims, as amended, recite that nucleic acid molecules include at least 40 nucleic acids or encode a fragment of 15 amino acids, and that molecules of these length are specific to the human TANGO405, and therefore, the claimed probes and primers would hybridize only to human TANGO405 polynucleotide. This argument is not persuasive because the human TANGO405 and mouse dectin-2 may not share 40 nucleic acids or 15 amino acids with 100% sequence identity, however, there is no way to predict whether the human TANGO405 may share such a sequence identity with other unknown proteins having distinct functional property. Further, it is well known in the art that it does not take 100% sequence identity for two molecule to hybridize, and therefore, without specifying regions *specific* for the human TANGO405 polynucleotide, a randomly selected fragment of 40 nucleotides from the human TANGO405 polynucleotide are likely bind to other molecules such as that encoding dectin-2. Additionally, it is not recognized in the art to use less homologous sequences or degenerate sequences as probes or primers.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1646

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 remains rejected, and the new claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 remains indefinite because the issue is *not* the term “*heterologous* polypeptide”, rather it is unclear what is the structural relationship of the heterologous polypeptide with said polypeptide, and whether the two nucleic acids are encoding a *fusion* protein or two *separate* proteins.

Claim 44 is indefinite for failing to adequately point out what applicants see as the invention, as it is unclear what “*a* polypeptide” is meant, and the host cell may produce polypeptides other than the polypeptide encoded by the transformed or transfected expression vector. The claim should be amended to indicate the identity of the polypeptide being produced.

The remaining claims are rejected for depending from an indefinite claim.

Conclusion:

No claim is allowed.

Advisory Information:

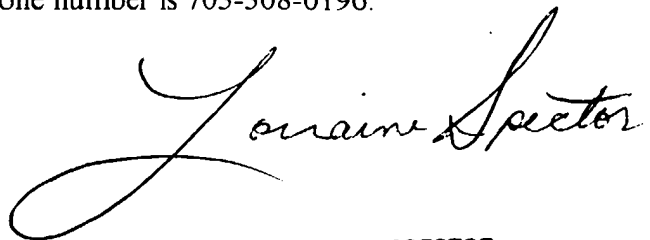
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0405.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink that reads "Lorraine Spector". The signature is written in a cursive, flowing style with a large initial "L".

**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
10/22/03